

part applies to you. We have the authority to order postmarket surveillance of any class II or class III medical device, including a device reviewed under the licensing provisions of section 351 of the Public Health Service Act, that meets any of the following criteria:

- (a) Failure of the device would be reasonably likely to have serious adverse health consequences;
- (b) The device is intended to be implanted in the human body for more than 1 year; or
- (c) The device is intended to be used to support or sustain life and to be used outside a user facility.

Subpart B—Notification

§ 822.5 How will I know if I must conduct postmarket surveillance?

We will send you a letter (the postmarket surveillance order) notifying you of the requirement to conduct postmarket surveillance. Before we send the order, or as part of the order, we may require that you submit information about your device that will allow us better to define the scope of a surveillance order. We will specify the device(s) subject to the surveillance order and the reason that we are requiring postmarket surveillance of the device under section 522 of the act. We will also provide you with any general or specific guidance that is available to help you develop your plan for conducting postmarket surveillance.

§ 822.6 When will you notify me that I am required to conduct postmarket surveillance?

We will notify you as soon as we have determined that postmarket surveillance of your device is necessary, based on the identification of a surveillance question. This may occur during the review of a marketing application for your device, as your device goes to market, or after your device has been marketed for a period of time.

§ 822.7 What should I do if I do not agree that postmarket surveillance is appropriate?

- (a) If you do not agree with our decision to order postmarket surveillance

for a particular device, you may request review of our decision by:

- (1) Requesting a meeting with the Director, Office of Surveillance and Biometrics, who generally issues the order for postmarket surveillance;
- (2) Seeking internal review of the order under § 10.75 of this chapter;
- (3) Requesting an informal hearing under part 16 of this chapter; or
- (4) Requesting review by the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

- (b) You may obtain guidance documents that discuss these mechanisms from the Center for Devices and Radiological Health's (CDRH's) Web site (www.fda.gov/cdrh/resolvingdisputes), and from the CDRH Facts-on-Demand system (800-899-0381 or 301-827-0111).

Subpart C—Postmarket Surveillance Plan

§ 822.8 When, where, and how must I submit my postmarket surveillance plan?

You must submit your plan to conduct postmarket surveillance within 30 days of the date you receive the postmarket surveillance order. For devices regulated by the Center for Biologics Evaluation and Research, send three copies of your submission to the Document Control Center (HFM-99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. For devices regulated by the Center for Drug Evaluation and Research, send three copies of your submission to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B Ammendale Rd., Beltsville, MD 20705-1266. When we receive your original submission, we will send you an acknowledgment letter identifying the unique document number assigned to your submission. You must use this number in any correspondence related to this submission.

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